REMARKS

Introductory Comments

Applicants herewith have submitted a petition to revive an unintentionally abandoned application under CFR 1.137(b), and also submitted a Request for Continued Examination (RCE) of this application upon grant of the petition to revive.

Applicants' Agent, Naishadh Desai, had consulted, via telephone, with Examiner Yunsoo Kim regarding the unintentional abandonment due to a docketing error, and the means to rectify the same on 05 April 2007. Examiner Kim had indicated that when the failure to respond action appears in her docket, she would issue a Notice of Abandonment, at which time the Applicants could file a petition to revive the abandoned patent application. Applicants have included this summary to provide a written record in the prosecution file history.

In the final Office Action under reply and the in the Advisory Action in response to Applicants' reply thereof, the Office has indicated the claims are rejected as follows: under 35 U.S.C. §102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 5,267,958) (claims 31-59); and under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Amendments to the Claims

Claims 1-74 were previously pending. Claims 1-30 and 60-74 were withdrawn from further consideration without prejudice. As a consequence, claims 31-59 remain under consideration.

Claim 31 is amended to recite "about 25 mg/mL to about 200 mg/mL", in order to more particularly point out and distinctly claim the invention. Support for the amendment is found, at least, at page 37, paragraphs [0159] to [0162], Figures 2A-2C, and Table II of the Specification.

Claim 31 is also amended to provide antecedent basis for dependent claim 43, by adding the phrase "pharmaceutically acceptable". Support for the amendment is found, at least, in claims 13, and 43.

Claim 31 is also amended to add the term "about", in order to more particularly point out and distinctly claim the invention. Support for the amendment is found, at page 23, lines 1-2 of the Specification.

Claim 58 is amended to recite the upper limit of the antibody composition as 200 mg/mL. Support for the amendment is found, at least, at page 37, paragraphs [0159] to [0162], Figures 2A-2C, and Table II of the Specification, and presently amended claim 31.

As support for the changes is found in the application as filed, no new matter is introduced and entry of these amendments is respectfully requested.

Rejection under 35 U.S.C. 102(b)

The Office Action has rejected claims 31-59 under 35 U.S.C. 102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958).

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

The Examiner begins her substantive remarks in the present Office Action by stating that the "patentability of the product does not depend on its method of production." Citing Andya et al. at claims 1-8 and 47 and column 17, lines 1-40, in particular, the Examiner alleges that the claimed antibody formulation and the referenced antibody formulation both comprise an antibody, diluent, buffer and sucrose as an excipient. The Examiner concludes that the "newly claimed product feature being visually clear upon reconstitution is [an] inherent property of the antibody formulations."

In response, Applicants point out that the claims, as presently amended, do not simply recite a reconstituted composition being "visually clear upon reconstitution." Instead, the claims recite (among other things) that the reconstituted composition "is a visually clear reconstituted composition within about 10 minutes of being formed." Emphasis added. In view of the different reconstitution times associated with the lyophilized formulations shown in the specification at

paragraph **[0162]** (which are also of the type disclosed in Andya et al.) and the spray dried formulations encompassed by the claims, it simply cannot be said that a visually clear reconstituted composition within about 10 minutes of being formed is "an inherent property of antibody formulations" generally.

Notwithstanding the claimed product feature (i.e., a composition that "is a visually clear reconstituted composition within about 10 minutes of being formed"), the Examiner attempts to bolster her position by pointing out perceived shortcomings of the sample test described at paragraph **[0162]**. Specifically, the Examiner perceives the comparison suffers from the following shortcomings: (a) the sample test was performed in distilled water and "cannot be extrapolated into the claimed diluent;" (b) the referenced antibody concentration is at 50mg/ml[1] and cannot be extrapolated into the claimed concentration range of about 1000 mg/ml; and (c) the specification discloses that the claimed diluent exceeds reconstituting time of 10 minutes at 190 mg/ml concentration and it is less likely to reconstitute 1000 mg/ml within 10 minutes.

In response to these perceived shortcomings, Applicants point out that concerns such as whether "deionized water" can be "extrapolated to the claimed diluent," whether the antibody concentration can be extrapolated to the claimed concentration range of from about 25 mg/mL to about 1000 mg/mL, and whether the composition is less likely to reconstitute within 10 minutes when the antibody concentration is 1000 mg/mL are immaterial to questions of novelty under 35 U.S.C. §102(b). Rather, what is material is whether the *claimed reconstituted compositions* are novel over the cited art. In addition, as to the point (c) of the Office Action (reconstitution time of more than 10 minutes at 190 mg/mL), Applicants also wish to point out that an alleged non-working example does not negate patentability where several working examples have been disclosed.

Again, Applicants emphasize that their claims require a reconstituted composition having the feature of visual clarity within about 10 minutes of being formed. Applicants have specifically demonstrated that reconstituted lyophilized compositions -- such as the type disclosed in Andya et al. -- will not inherently become a visually clear reconstituted composition within about 10 minutes of being formed. Further, a close reading of Andya et al. only reveals that the "time required for reconstitution will depend, e.g., on the type of diluent, amount of excipient(s) and protein." See

[1] Although it appears the Examiner indicates that "the sample test as in [0162]" had an antibody concentration of 50 mg/mL, paragraph [0162] actually describes a composition having a concentration of 200 mg/mL.

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Andya et al. at Column 17, lines 23-25. In addition, Andya et al. fails to disclose the feature of a spray-dried powder, a feature recited in the only pending independent claim. Consequently, as the cited art fails to teach each and every feature recited in the claims, the rejection of claims 31-59 under 35 U.S.C. 102(b) should be removed. Reconsideration and removal of the rejection are respectfully requested.

Rejection under 35 U.S.C. 112, First Paragraph

The Office Action has rejected claims 31-59 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with its requirements.

Without commenting on the validity of the rejection and merely to expedite prosecution, Applicants have amended claim 31 to recite the phrase "within about 10 minutes" which, as the Office Action agrees is supported by the Specification.

CONCLUSION

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 631-3286.

Respectfully submitted,

Date: 30 MAY 2007 By: _____

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